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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,503	11/02/1999	THOMAS R. CECH	15389-002611	1130

34151 7590 10/18/2005

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/432,503	**Applicant(s)** CECH ET AL.	
	Examiner Jon Eric Angell	**Art Unit** 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *16 August 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *41-57 and 74-82*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *58-62 and 65-73*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Jon Eric Angell

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments filed 8/16/05 have been fully considered, but are not persuasive. The claims are rejected under 35 USC 112, first paragraph because the claims are drawn to a method of increasing proliferative capacity of a mammalian cell by contacting the cell with an adenovirus vector that expresses a DNA sequence that encoding a telomerase reverse transcriptase protein containing the the telomerase T motif, whereby introducing the recombinant polynucleotide into the cell increases the proliferative capacity of the cell. As previously indicated the claims are very broad and encompass increasing the proliferative capacity of a cell in vitro or in vivo. Looking to the specification for guidance, it is clear that the ONLY contmeplated use for "increasing the proliferative capacity" of a cell in vivo is for treating disease. It is noted that the claims to do not indicate that the method is for treating any specific disease. However, the specification contemplates treating a myriad of different diseases including cancer, hair loss, graying of hair, Alzheimer's disease, stroke, atherosclerosis, diabetes, etc. (see pages 98-101). Therefore, given the broadest reasonable interpretation consistent with the specification, the claims encompass treating any of the aforementioned diseases, as well as all other disease disclosed in the specification, by administering the adenoviral vector by any route of administration (including systemic adminstration) to a subject. The reasons why the claims are not enabled for their full scope were clearly set forth in a previous Office Action (e.g., see the Office Action mailed on 3/17/2005). Applicants arguments filed 8/16/05 address specific aspects of the rejection, but do not overcome the rejection as a whole because nothing presented by Applicants have indicated that the specification provides enablement for the full scope encompassed by the claims. With respect to Applicants arguments that the claims have been amended to indicate that vector expresses TRT, the amendment is acknowledged and does overcome this particular aspect of the rejcetion. With respect to Applicants arguments that most nucleated mammalian cells constituitively express telomerase RNA component rendering it unnecessary to indicate in the claims that the target cells actually express telomerase RNA component, Applicants argument is not persuasive. Applicants refer to two references in support of their argument: Bodnar (Science 1998) and Harley (Oncogene 2002), which have been previously cited by Applicants. The Examiner has carefully reviewed the indicated references and can not find support for Applicants argument that most nucleated mammalian cells constituitively express telomerase RNA component. It is noted that Applicants have not indicated the exact location in the references where the indicated teachings can be found. Therefore, Applicants arguments do not overcome the requirement that the target cells must express telomerase RNA component. With respect to Applicants arguments that safety of the method of therapeutic compounds can ultimately only be determined by human clinical trials which under the perview of the Food and Drug Administration (FDA), it is acknowledged that the FDA determines safety and effiicacy of therapeutic compounds. However, the citred prior art is an indication that the claimed method requires further, undue, experimentation in order to be fully enabled. As such, Applicants arguments are not persuasive. Applicants also argue that the claims do not require the treatment of disease, only the increase in proliferative capacity of the target cell and further indicate that animal models have been provided demonstrating that the disclosure is enabling for increasing proliferative capacity for treting skin wound and liver cirrhosis. In response, it is acknowledged that the claims do not require the treatment of a particular disease, however, the only contemplated use for the claimed method, in vivo, is for treating disease. Applicants assert that the user need not be treating a disease in order to use the claimed invention, however, the specificaiton does not indicate ANY other use for increasing the proliferative capacity of a cell in vivo. If Applicants are aware of any other disclosed use for the claimed method, in vivo, they are asked to identify the non-treatment use of the claimed method and to indicate where in the specification (the specific page and line numbers) where support for the non-treament methods can be found. With respect to Applicants assertion animal models have been provided, it is noted that the animal model are not apropriate models for gene therapy for the reasons indicated in the previous Office Actions (e.g., see the Office Action mailed 3/14/2005). Applicants also argue that the Ostler reference indicates that rodent models are in fact more rigorous for telomere therapy. In response, it is pointed out that Ostler explicitly teaches "It is unlikely however that this [telomere-driven senescence] mechanism operated in rodent species". If it is unlikley that telomere-driven senescence operates in rodents, as evidences by the teaching of Ostler that "some rodent fibroblasts have been shown to undergo senescence in the presence of active telomerase", it is clear that the rodent is not a proper animal model. The Applicants also assert that the Examiner has the Expert Declaration out-of-hand. The Examiner disagrees with this assertion. The Declaration was properly addressed in the Office Action mailed 3/17/2005. In conclusion it is pointed out that the claims are rejected because the specification has not provided an enabling disclosure for the full scope of the claims. Specifically, the specification does not provide an enabling disclosure for treating disease using the claimed method, which is the ONLY contemplated in vivo use for the claimed method. Applicants arguments have not overcome the rejection because the have not persuasively argued that specification does provide an enabling disclosure for treating disease by performing the claimed method.